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PHA 42631.1 (01381/2/US)  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson

Serial No. 10/828,683

Filed April 21, 2004

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR AND A SODIUM ION CHANNEL BLOCKER FOR THE TREATMENT OF PAIN, INFLAMMATION OR INFLAMMATION MEDIATED DISORDERS

June 28, 2004

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VIRGINIA 22313-1450

SIR:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicant submits herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicant believes that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,

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EJH/cms  
Mail Stop Amendment

PTO/SB/08A

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)



				Complete if Known	
				Application Number	10/828,683
				Filing Date	April 21, 2004
				Confirmation Number	
				First Named Inventor	Diane T. Stephenson
				Group Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket No.	PHA 42631.1 (01381/2/US)

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
1	5,466,823			Talley et al	11/14/1995
2	5,521,207			Graneto	05/28/1996
3	5,633,272			Talley et al	05/27/1997
4	5,932,598			Talley et al	08/03/1999
5	6,034,256			Carter et al	03/07/2000
6	6,077,850			Carter et al	06/20/2000

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
7	WO	91/08760			Brigham and Women's Hospital	06/27/1991	
8	WO	92/16192			Amgen Inc.	10/01/1992	
9	WO	98/03484			Merck Frosst Canada Inc.	01/29/1998	
10	WO	00/24719			Abbott Laboratories	05/04/2000	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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				Attorney Docket No.	PHA 42631.1 (01381/2/US)

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	11	ELLIOTT, "Slow Na+ Channel Inactivation and Bursting Discharge in a Simple Model Axon: Implications for Neuropathic Pain", Brain Research, 1997, 754: 221-226	
	12	GIERSE et al, "Expression and Selective Inhibition of the Constitutive and Inducible Forms of Human Cyclo-oxygenase", Biochemical Journal, 1995, 305: 479-484	
	13	HARGREAVES et al, "A New and Sensitive Method for Measuring Thermal Nociception in Cutaneous Hyperalgesia" Pain, 1988, 32: 77-88	
	14	LAIRD et al, "Analgesic Activity of a Novel Use-Dependent Sodium Channel Blocker, Crobenetine, in Mono-Arthritic Rats" British Journal of Pharmacology, 2001, 134(8): 1742-1748	
	15	NEWMAN, "Aerosols and the Lung: Clinical and Experimental Aspects", Chapter 9 - "Therapeutic Aerosols", Butterworths, London, England, 1984, p. 197-224	
	16	SIEGMUND et al, "A Method for Evaluating both Non-Narcotic and Narcotic Analgesics", Proceedings of the Society for Experimental Biology and Medicine, 1957, 95: 729-31	
	17	WINTER et al, "Carrageenin-Induced Edema in Hind Paw of the Rat as an Assay for Antiinflammatory Drugs", Proceedings of the Society for Experimental Biology and Medicine, 1962, 111(3): 544-547	

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